

## **REMARKS/ARGUMENTS**

Claims 1-2, 6-25, 27-33, and 37-43 are pending in this application, with claims 1, 25, 32, and 43 being the only independent claims. Reconsideration of the application in view of above-identified in view of the above amendments and the following remarks is respectfully requested.

### **Claim Amendments**

Independent claim 1 is amended to recite “said shield being movable by interaction with an area proximate a needle cannula insertion point on a patient’s skin from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament” and “said pin moving from a first pin position along said entry track at least to the intersection and into a second pin position in said lock-out track during movement of said shield from the first position to the second position, and said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient, said pin moving along said lockout track from said second pin position to a third pin position solely by the urgency of said urging member during movement of said shield from said second position to said third position, wherein said forward tip of said needle cannula is covered by said shield when said shield is in said third position”. Support for this amendment is found in the specification at paragraph 0022 and Fig. 80 which shows the front end 122 of shield 22 contacting the skin 80 of the patient proximate the needle insertion point. Support is also found at paragraphs 0022-0023; and Fig. 5 which describe and show how the pin 38 enters a central position 74 and then a rear end 76 of the lockout track when the needle is inserted and is urged from the rear end 76 to a forward area 78 in the lockout track when the needle is removed.

The remaining independent claims 25, 32, and 43 are similarly amended.

Dependent claims 5 and 36 are canceled without prejudice or disclaimer.

### **Rejections of Claims**

Claims 1, 2, 5-23, 25, 27-33, and 36-43 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,429,612 (Berthier).

Claim 24 stands rejected under 35 U.S.C. §103 as unpatentable over Berthier.

Independent claim 1 recites “said pin moving from a first pin position along said entry track at least to the intersection and into a second pin position in said lock-out track during movement of said shield from the first position to the second position, and said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient” and “said pin moving along said lockout track from said second pin position to a third pin position solely by the urgency of said urging member during movement of said shield from said second position to said third position”.

Accordingly, independent claim 1 requires (1) that the pin moves from the first pin position to the second pin position as the shield moves against the urgency of the urging member by interaction with the patient’s skin during insertion of the needle, and (2) that the pin moves from the second position to the third pin position solely by urgency of the spring when the shield moves by the urging member from the second position to the third position upon removal of the needle from the patient.

Berthier fails to disclose these limitations because Berthier discloses that after a shield is moved from a first position to a second position against an urgency of a spring and the pin of the shield is in a second pin position, the spring does not urge the shield from the second position to a third position. Instead, the shield of Berthier must be rotated so that the pin of the

shield is moved from the second pin position to a further position before the spring is able to urge the shield to a third position which covers the needle, wherein the rotation is not against the urgency of the spring.

Berthier discloses a syringe having a needle protector 8 arranged over a cylindrical slideway 7 with a track arrangement having a U-shaped groove 22 with two branches 23, 24 connected by a circumferential groove 25 (see col. 4, lines 35-39 of Berthier). A resilient tongue (i.e., pin) 26 of the needle protector 8 enters the track arrangement and moves along branch 23 against the urgency of a spring 20. Thus, the second position is the point where branches 23 and 25 meet. The Examiner has indicated that the element 25 of Berthier is considered part of the lockout track. However, the urgency of the spring 20 does not urge the shield from the second position to the third position when the pin is at this position. Rather, Berthier discloses that the needle protector 8 first has to be rotated from the second position to a further position in which the resilient tongue 26 is aligned with the branch 24 before the resilient tongue 26 can be urged to the third position in which the tip of the needle is covered (see col. 4, lines 53-58 of Berthier).

Since the tracks of Berthier are arranged so that the needle protector 8 must be rotated manually before the shield can be urged by the spring 20 to the third position from the second position, Berthier fails to disclose, teach or suggest “said pin moving along said lockout track from said second pin position to a third pin position solely by the urgency of said urging member during movement of said shield from said second position to said third position”. Thus, independent claim 1 is not anticipated by or unpatentable over Berthier.

Independent claims 25, 32, and 43 include similar limitations to independent claim 1 and are allowable for at least the same reasons as is independent claim 1.

Dependent claims 2, 6-24, 27-31, 33 and 37-42, each being dependent on one of independent claims 1, 25, and 32, are deemed to be allowable for at least the same reasons expressed above with respect to independent claims 1, 25 and 32, as well as for the additional recitations contained therein.

The application is deemed to be in condition for allowance and notice to that effect is solicited.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,  
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